



## UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,259	09/12/2003	Ben-Zon Dolitzky	1662/568077	7774
26646	7590	12/16/2005	EXAMINER	
KENYON & KENYON ONE BROADWAY NEW YORK, NY 10004			CHANG, CELIA C	
		ART UNIT		PAPER NUMBER
		1625		

DATE MAILED: 12/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/661,259	DOLITZKY ET AL.	
	Examiner Celia Chang	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 21 March 2005.

2a) This action is FINAL.                            2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-10 and 121-131 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 1-10 and 121-131 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.

4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## DETAILED ACTION

1. This application is a divisional of SN 118,807.

Claims 11-120 have been canceled. Claims 121-131 have been added. Claims 1-10, 121-131 are pending.

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 6-9 are rejected under 35 U.S.C. 102(a) as being anticipated by Kumar et al. WO 00/71124 (cited on 1449).

See examples 1-5 for making fexofenadine hydrochloride amorphous form using spray drying.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-10, 121-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumar et al. WO 00/71124 in view of Okabe et al. CA 114:54120 or Williams et al. US 6,862,890.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

Kumar et al. '124 disclosed anticipatory process of the base claims 6-9 as delineated supra and hereby incorporated by reference.

*Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)*

The difference between the more limited claims 1-5 and 10, 121-131 and the prior art spray drying process of obtaining amorphous fexofenadine hydrochloride is that the claims are limited to the particular solvent THF or evaporation process for solvent removal.

Okabe et al. CA 114 disclosed that both spray dryer and evaporator are alternative apparatus for solvent removal. Williams et al. '890 taught that in pharmaceutical particulation processes of fexofenadine hydrochloride (see col. 15 line 39), spray drying is a solvent removal procedure analogous to other conventional solvent removing procedures (see col. 1 lines 26-27, col. 2 lines 59-60) and optionally ethanol, methanol or tetrahydrofuran are choices of solvents (see col. 4 lines 51-56).

*Finding of prima facie obviousness—rational and motivation (MPEP§2142-2143)*

On having ordinary skill in the art in possession of the above references are in possession of the claims because Kumar et al. disclosed proven process of obtaining amorphous fexofenadine hydrochloride from solution by solvent removing and Williams or Okabe taught the proven interchangeability among the different solvents and solvent removing techniques conventional in the art. In absence of unexpected results, there is nothing unobvious in picking certain solvent or solvent removing choice among the proven operable alternatives.

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10, 121-131 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carr et al. US 4,254,129, 4,285,957, or WO 95/31437 (all cited on 1449) or Woosley US 5,375,693 in view of Lieberman, Suzuki et al. CA 91:44479, Corrigan et al. CA 98:166814, Nuernberg CA 86:8603 and Sato CA 110:179429 supplemented with US 5,990,127.

*Determination of the scope and content of the prior art (MPEP §2141.01)*

The primary references disclosed fexofenadine hydrochloride:

See Carr '129, col. 13, example 3,

Carr '957 col. 13, example 3  
WO 95/31429 claims 10-11, 13-15, 17-19, p. 11 lines 22-29 solvents  
Woosley et al. '693, col. 10, example 1B, and solvent.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the prior art and the instant claims is that the amorphous form or process of spray dry or evaporation etc. for preparing an amorphous form was not explicitly disclosed. However, Lieberman, Suzuki, Corrigan, Nuernberg or Sato provided perponderous of evidence that spray drying or evaporation process are size reduction processes for pharmaceutical products and such size reduction would enhance drug dissolution thus bioavailability (see Lieberman).

Finding of prima facie obviousness—rational and motivation (MPEP §2142-2143)

One having ordinary skill in the art in possession of the above references would be motivated to prepare the amorphous form of the drug because process of preparing the named compound is conventionally explicitly taught using the claimed solvents. One skilled in the art would be motivated to carry out the prior art process employing spray drying or evaporation since it was clearly suggested by the prior art that spray drying and evaporation are size reduction routine procedure in formulation which enhances drug dissolution, also such process would inherently produce the amorphous form. Further, the claimed product, when prepared from a biological resource, has been prepared routinely employing the procedure lyophilization which is solvent removal, supplied evidence that solvent removal are routine procedure in drug formulation.

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(g)(1) during the course of an interference conducted under section 135 or section 291, another inventor involved therein establishes, to the extent permitted in section 104, that before such person's invention thereof the invention was made by such other inventor and not abandoned, suppressed, or concealed, or (2) before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it. In determining priority of invention under this subsection, there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Claims 1-10, 121-131 are provisionally rejected under 35 U.S.C. 102(e) or (g) as being anticipated by US 2005/0165056.

See page 2, examples 5-6 and page 3 claims 15-19.

This is a provisional rejection since the claims or the pre-grant publication has not yet been patented. Please note that the Kirsch pre-grant publication is entitle to priority benefit of a NAFTA country.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang  
Dec. 1, 2005

  
Celia Chang  
Primary Examiner  
Art Unit 1625